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Enclosure

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Patent Claims

1. Liquid formulation which comprises human
interferon- β as active ingredient in a
concentration of up to 25 MU/ml and a buffer for
10 setting a pH of 5 to 8, is free from human serum
albumin and after storage for 3 months at 25°C
shows a long-term stability of the biological in
vitro activity of at least 80% of the initial
activity, with the proviso that the formulation
15 does not comprise any acidic amino acids, arginine
or glycine in amounts of between 0.3 and 5% by
weight.
3. Liquid formulation which comprises human
20 inferferon- β as active ingredient, a buffer for
setting a pH of 5 to 8, and one or more amino
acids and shows after storage for 3 months at 25°C
a long-term stability of the biological in vitro
activity of at least 80% of the initial activity,
25 with the proviso that the formulation does not
comprise any acidic amino acids, arginine or
glycine in amounts of between 0.3 and 5% by
weight.

23. Pharmaceutical preparation according to Claim 21 or 22 in the form of unit doses of 1 to 25 MU.
- 5 25. Process for improving the shelf life of a liquid formulation which comprises human interferon- β as active ingredient and a buffer for setting a pH of 5 to 8,
characterized in that
a formulation without human serum albumin or/and
10 with one or more amino acids is used, with the proviso that the formulation does not comprise any acidic amino acids, arginine or glycine in amounts of between 0.3 to 5% by weight.
- 15 26. Process according to Claim 25,
characterized in that
the improved shelf life encompasses improved long-term stability of the biological in vitro
activity, of the chemical integrity or/and of the
20 physical integrity.

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ART 34 AMDT

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422 Rec'd PCT/PTO--23 MAR 2009

New Claim 2

- 5 2. Liquid formulation according to Claim 1,
characterized in that
it comprises a buffer for setting a pH of 6 to
7.2.